§ 640.83 General requirements.

(a) *Preservative.* The final product shall not contain a preservative.

(b) *Storage of bulk solution.* After all processing steps have been completed, the sterile bulk solution shall be stored in a manner that will ensure the continued sterility of the product, and at a temperature that shall not exceed the recommended storage temperature of the final product prescribed in § 610.53 of this chapter.

[42 FR 27582, May 31, 1977]

§ 640.84 Labeling.

In addition to the labeling requirements of §§ 610.60, 610.61, and 610.62 of this chapter,

(a) The container and package labels shall contain the following information:

(1) The osmotic equivalent in terms of plasma, and the sodium content in terms of a value or a range in milliequivalents per liter;

(2) The cautionary statement placed in a prominent position on the label, ''Do Not Use if Turbid. Do Not Begin Administration More Than 4 Hours After the Container Has Been Entered.'';

(3) The need for additional fluids when 20 percent or 25 percent albumin is administered to a patient with marked dehydration;

(4) The protein content, expressed as a 4 percent, 5 percent, 20 percent, or 25 percent solution.

(b) The type of source material, expressed as venous plasma, placental plasma, or both, used to manufacture the final product shall appear on either the container or package label or in the package insert.

[42 FR 27582, May 31, 1977, as amended at 49 FR 2244, Jan. 19, 1984]

Subpart I—Plasma Protein Fraction (Human)

SOURCE: 42 FR 27583, May 31, 1977, unless otherwise noted.

§ 640.90 Plasma Protein Fraction (Human).

(a) *Proper name and definition.* The proper name of the product shall be Plasma Protein Fraction (Human). The product is defined as a sterile solution of protein composed of albumin and globulin, derived from human blood.

(b) *Source material.* The source material of Plasma Protein Fraction (Human) shall be blood, plasma, or serum from human donors determined at the time of donation to have been free from disease-causative agents that are not destroyed or removed by the processing method, as determined by the medical history of the donor and from such physical examination and clinical tests as may appear necessary for each donor at the time the blood was obtained. When source material is a product for which additional standards are effective, the requirements of those additional standards shall determine the propriety of the material for use in the production of Plasma Protein Fraction (Human). When no additional standards are effective with respect to source material for the production of Plasma Protein Fraction (Human), such source material shall:

(1) Be collected by a procedure which is designed to assure the integrity and to minimize the risk of contamination of the source material. The manufacturer of Plasma Protein Fraction (Human) shall ensure that the collection procedure shall be as described in its license;

(2) Be identified to relate it accurately to the individual donor and to the dates of collection;

(3) Not contain a preservative; and

(4) Be stored and transported in a manner designed to prevent contamination by microorganisms, pyrogens, or other impurities.

(c) *Additives in source material.* Source material shall not contain an additive unless it is shown that the processing method yields a final product free of the additive to such extent that the continued safety, purity, potency, and effectiveness of the final product will not be adversely affected.

§ 640.91 Processing.

(a) *Date of manufacture.* The date of manufacture shall be the date of final sterile filtration of a uniform pool of bulk solution.

(b) *Processing method.* The processing method shall not affect the integrity of